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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,326	09/25/2003	Deping Wang	RIB-007	1502
51414	7590	06/29/2005	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			GRAZIER, NYEEMAH	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,326

Applicant(s)

WANG ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8,14-17,23,25,26,28 and 32-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9-13,29 and 30 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5,9-13,18-22,24,27 and 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/23/03-4/11/05.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

I. PRIORITY

This application claims priority to and the benefit of U.S. Provisional Applications Serial Nos. 60/414,207 filed on September 26, 2002 and 60/448,216 filed on February 19, 2003.

However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Examiner has reviewed the provisional applications that the Applicant claims benefit of priority to. However, there are limitations in claim 1 that are not supported in the original disclosure. (See Section V. below). Applicant is invited to show the requisite support in the original filed disclosure to which Applicant claims the benefit of priority.

II. ACTION SUMMARY

Claims 1-42 are currently pending in the instant application and are subject to the restriction as described below. **Claims 3, 6, 7, 8, 14-17, 23, 25, 26, and 28** are not drawn to the elected species and are therefore withdrawn from consideration and examination. **Claims 32-42** are non-elected claims and are therefore withdrawn from consideration and examination.

Claims 1, 2, 4, 5, 9, 10, 11, 12, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Phillips, et al. **Claims 29 and 30** are rejected under 35 U.S.C. 112, second

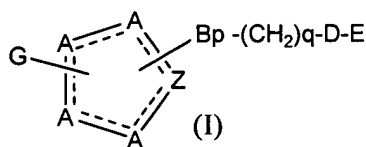
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paragraph, as being indefinite. **Claim 13** is objected to under 35 U.S.C. 112, second paragraph for lack of antecedent basis. **Claims 1, 2, 4, 5, 9-13, 18-22, 24, 27, 29-31** are objected to as containing non-elected subject matter. Lastly, **Claims 2, 4, 5, 9-13, 18-22, 24, and 27** are objected to as being dependent upon a rejected base claim.

III. Restriction

The Markush group set forth in the claims includes both independent and distinct inventions, and patentable distinct compounds or species within each invention. However, the instant application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contain a plurality of patentable distinct compounds, also far too numerous to list individually. Restriction to one of the following Inventions is required pursuant to 35 U.S.C. § 121, wherein an Invention is a set of patentable distinct inventions of a broad statutory category.

- I. Claims 1-31, drawn to compounds having the formula (I),



, classified in various subclasses of various classes

such as class 544, subclass 137, class 548, subclass 229, class 546, subclass 256, for example.

- II. Claim 32-39, drawn to a method of treatment, classified in class 514, subclass 377.

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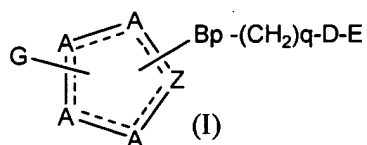
- III. Claim 40, drawn to process of making compounds according to claims 1-30, classified in class 514, subclass 377.
- IV. Claims 41-42, drawn to a medical device, classified in class 604, subclass 19, for example.

Markush Claims

A provisional election of a species is required because the Markush-type claims of the instant application include distinct independent inventions. Restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. See In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); See also Ex Parte Hozumi, 3 USPQ2d 1059 (BPAI 1984). Absent evidence that subject matter of the Markush-type claim lacks unity of invention, the Office may not merely “refuse to examine that which applicants regard as their invention.” See M.P.E.P. § 803.02; In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Additionally, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. §103. **Therefore, in addition to an election of one of the abovementioned Inventions, restriction is further required under 35 U.S.C. § 121.**

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If Invention I or III is elected, election of a single species is further required, including an exact definition of each substitution on the base molecule, Formula (I), wherein a single member at each substituent group is selected. For example, in the instant application, the base molecule of



Formula (I), has *inter alia*, substituent “A,” where “A”, at each occurrence, independently is carbon, carbonyl, or nitrogen provided that at least one is carbon” (Instant Application SN 10/671,326, Claim 1.) Applicant must select a single substituent representing “A” at each position on the ring. This process is repeated for each variable so that a single compound is identified.

If Invention II is elected, then election of a specific method of use is required. For example: A method of treating:

- A. fungal infection;
- B. parasitic disease;
- C. microbial disease;
- D. viral infection, etc.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound. The elected compounds should be similar that they will encompass the same inventive concept and reduction to practice. The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in

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related subclasses. Examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds, which are so similar, within the same inventive concept and reduction to practice. Markush claims require sufficient support in the disclosure for each member of the Markush group. See MPEP § 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the core structure as the selected species must be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Invention I-III are related as process of making product, product and the method of use of said0 products. However, there are multiple distinctive inventions in each Group and among the three groups. Inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product M.P.E.P. § 806.05.

In the instant case, Invention I is distinct from Invention II. Invention I, directed to the products of the compounds of formula (I), is distinct from Invention II directed to the method of treatment using the compounds of the invention because the method of treating microbial infections, for example, can be accomplished with products other than the product of Formula (I). See e.g., Tsiodras et al. (2001) LANCET 358: 207; Gonzales et al. (2001) LANCET 357: 1179.

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Invention II is unrelated to Invention III. Invention II, directed to the method of treatment using the compounds of the invention of formula (I), is unrelated to Invention III, directed to the process of making the compound of the invention. The inventions are two separate statutory subject matter. The process of making the compounds of claim 1 is classified in various classes and subclasses, class 544, subclass 137, class 548 subclass 229, class 546, subclass 256, for example. The method of treatment using the various compounds are classified in class 514 and the subclasses vary depending on the compound, for example, subclasses 376, 231.8, and 336.

Invention I is distinct from Invention III. Invention I, directed to the products of the compounds of formula (I), is distinct from Invention III, directed to the process of making the compound of the invention. Inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product as claimed can be practiced with another materially different product or (2) the product as claimed can be made by a materially different process. M.P.E.P. § 806.05. In the instant case, the process of making anti-infective agent that contains the genus of the instant invention can be made by a different process. See e.g., Phillips, et al. Synthesis and Antibacterial Activity of 5-Substituted Oxazolidinones, Bioorg. Med. Chem. 2003, 11(1), pp. 35-41.

Invention I, II and III are unrelated to Invention IV. Invention IV is drawn to a medical device. Medical devices are classified in a separate classification category; for example, class 604, subclass 19.

Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas.

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Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, the restriction as set forth in the instant application is proper.

In sum, each Group listed above has a diverse chemical structure, different chemical properties, different modes of action, and different effects and reactive conditions and is therefore recognized in the art as being distinct from one another. MPEP §§ 806.04, 808.01. Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The rebuttable presumption, that similar chemical structures behave similarly, may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lahu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Advisory of Rejoinder

The Examiner has required restriction between a product and method of use claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable

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product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found

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patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Pursuant to M.P.E.P. § 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed

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product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

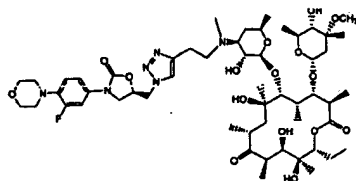
Telephone Inquiry

During a telephone conversation with Duncan Greenhalgh, Esquire on June 16, 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-31, directed to a product. Mr. Greenhalgh also elected Example Compound 149 (Table 2, p. 170) as a species of the genus. Claims 32-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is reminded that he/she is required to affirm this election when responding to this Office Action.

IV. ELECTION

Scope of the Elected Subject Matter Based on Example 149

Applicant's telephonic election with traverse of the compound 149,



(See table 2, p. 170 of Specification) in response to the requirement to restrict the products of Formula (I) is acknowledged. Therefore the elected invention for search and examination is the products of Formula (I) as recited in instant **Claim 1** wherein:

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"A" is at two occurrences are nitrogen atoms, provided that the remaining "A" are carbon;

"Z" is nitrogen; wherein **Bp-(CH₂)_q-D-E** is a substitution on the nitrogen atom;

"B" is selected from the group consisting of O, NR₂, S(O)_r, C=O, C=S, and C=NOR₃;

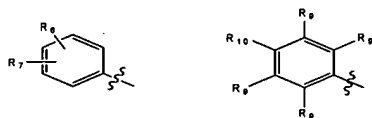
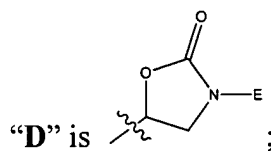
"n" is 1, 2, 3, or 4;

"p" is 0;

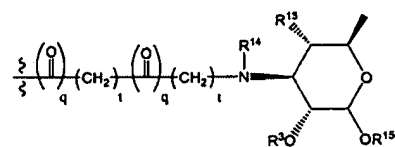
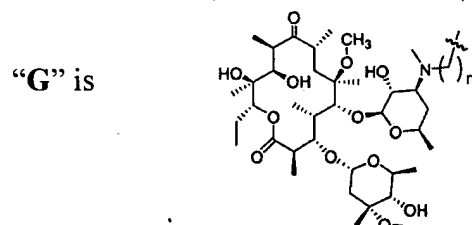
"q" is 0 or 1

"t" at each occurrence is 0, 1, 2, or 3;

"r" is 0



"E" is ;



or the formula (o) or (p) as set forth in claim 1, C1-4 alkyl, C5-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, C1-8 alkoxy, C1-8 alkylthio, C1-8 acyl, saturated, unsaturated or aromatic C5-10 carbocycle;

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“J” is selected from the group consisting of: OC(O), OC(O)O, OC(O)NR₂, C(O)NR₂, NR₂C(O), NR₂C(O)O, NR₂C(O)NR₂, NR₂C(NH)NR₂, and S(O)r;

“R₂” at each occurrence, independently is selected from the group consisting of hydrogen, S(O)rR₄, formyl, C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, C1-8 alkoxy, C1-8 alkylthio, C1-8 acyl, saturated, unsaturated or aromatic C3-8 carbocycle;

wherein:

C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, C1-8 alkoxy, C1-8 alkylthio, C1-8 acyl, saturated, unsaturated or aromatic C3-8 carbocycle groups are optionally substituted with one or more moieties selected from the group consisting of carbonyl, F, Cl, Br, I, CN, NO₂, NR₃R₃, OR₃, S(O)rR₄, S(O)rNR₃R₃, C(O)R₃, C(O)OR₃, OC(O)R₃, C(O)NR₃R₃, OC(O)NR₃R₃, aryl, substituted aryl;

“R₃” is selected from the group consisting of hydrogen, C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, C1-8 acyl, saturated, unsaturated or aromatic C3-8 carbocycle, said groups being optionally substituted with one or more moieties selected from the group consisting of carbonyl, F, Cl, Br, I, CN, NO₂, NR₆R₆, OR₆, S(O)rR₆, S(O)NR₆R₆, C(O)R₆, C(O)OR₆, OC(O)R₆, C(O)NR₆R₆, OC(O)NR₆R₆, C1-6acyl, aryl, substituted aryl;

“R₄” is selected from the group consisting of H, NR₃R₃, NR₃OR₃, NR₃NR₃R₃, NHC(O)R₃, C(O)NR₃R₃, N₃, C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, saturated, unsaturated or aromatic C3-8 carbocycle;

“R₆” is selected from the group consisting from the group consisting of hydrogen, C1-6 alkyl, C1-6 alkenyl, C1-6 alkynyl, aryl, substituted aryl and acyl;

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“**R7**” is a saturated 6-membered nitrogen linked heterocycle containing nitrogen and oxygen as the only two heteroatoms;

“**R8**” is selected from a group consisting of hydrogen, F, Cl, Br, I, CN, NO₂ or OR₆, aryl, substituted aryl, C1-6 alkyl, optionally substituted with one or more moieties selected from the group consisting of aryl, substituted aryl, F, Cl, Br, I, CN, NO₂, and OR₆;

“**R9**” at each occurrence, independently is selected from the group consisting of: H, F, Cl, Br, and I.

“**R10**” is selected from the group consisting of: a saturated N-linked 6 member heterocycle containing nitrogen and oxygen heteroatoms in the 1-4 position.

“**R12**” is selected from the group consisting of: NR₂R₂, OR₃, OC(O)R₂, OC(O)OR₃, NR₂C(O)R₂, NR₂C(O)NR₂R₂, NR₂C(S)NR₂R₂ and NR₂C(=NR₂)NR₂R₂;

“**R13**” is selected from the group selected from hydrogen, carbonyl, formyl, F, Cl, Br, I, CN, NO₂, OR₃, S(O)rR₅, S(O)N=R₃, C(O)R₂, C(O)OR₃, OC(O)R₂, C(O)NR₂R₂, OC(O)NR₂R₂, C(=NR₁₂)R₂, C(R₂)(R₂)OR₃, C(R₂)(R₂)OC(O)R₂, C(R₂)(OR₃)(CH₂)rNR₂R₂, NR₂R₂, NR₂OR₃, N(R₂)C(O)R₂, N(R₂)C(O)OR₃, N(R₂)C(O)NR₂R₂, N(R₂)S(O)rR₅, C(OR₆)(OR₆)R₂, C(R₂)(R₃)NR₂R₂, C(R₂)(R₃)NR₂R₁₂, =NR₁₂, C(S)NR₂R₂, N(R₂)C(S)R₂, OC(S)NR₂R₂, N(R₂)C(S)OR₃, N(R₂)C(S)NR₂R₂, SC(O)R₂, C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, C1-8 alkoxy, C1-8 alkylthio, C1-8 acyl, saturated, unsaturated, or aromatic C5-10 carbocycle,

wherein C1-8 alkyl, C2-8 acyl, saturated, unsaturated, or aromatic C5-10

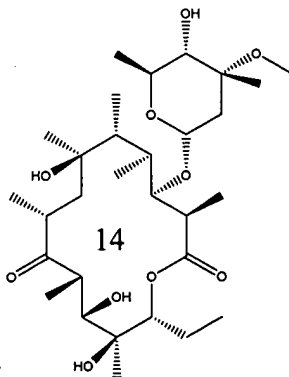
carbocycle groups are optionally substituted with one or more moieties selected from the group consisting of: carbonyl, formyl, F, Cl, Br, I, CN, NO₂, OR₃, S(O)rR₅, S(O)N=R₂,

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C(O)R₂, C(O)OR₃, OC(O)R₂, C(O)NR₂R₂, OC(O)NR₂R₂, C(=NR₁₂)R₂,
 C(R₂)(R₂)OR₃, C(R₂)(R₂)OC(O)R₂, C(R₂)(OR₃)(CH₂)_rNR₂R₂, NR₂R₂, NR₂OR₃,
 N(R₂)C(O)R₂, N(R₂)C(O)OR₃, N(R₂)C(O)NR₂R₂, N(R₂)S(O)_rR₅, C(OR₆)(OR₆)R₂,
 C(R₂)(R₃)NR₂R₂, C(R₂)(R₃)NR₂R₁₂, =NR₁₂, C(S)NR₂R₂, N(R₂)C(S)R₂,
 OC(S)NR₂R₂, N(R₂)C(S)OR₃, N(R₂)C(S)NR₂R₂, SC(O)R₂, C1-8 alkyl, C2-8 alkenyl,
 C2-8 alkynyl, C1-8 alkoxy, C1-8 alkylthio; C1-8 acyl, saturated, unsaturated, or aromatic
 C3-10 carbocycle optionally substituted with one or more R₇ groups.

“R₁₄” is selected from the group consisting of: (a) H, (b) C1-6 alkyl, (c) C2-6 alkenyl,
 (d) C2-6 alkynyl, (e) C(O)R₃, (f) C(O)C1-6 alkyl-R₃, (g) C(O)C2-6 alkenyl-R₃, (h) C(O)C2-6
 alkynyl-R₃, C1-6 alkyl-J-R₃, (j) C2-6 alkenyl-J-R₃ and (k) C2-6 alkynyl-J-R₃; wherein any of
 (b)-(d) is optionally substituted with one or more substituents selected from the group consisting
 of: F, Cl, Br, I, aryl, substituted aryl, OR₃, OC1-6 alkyl-R₂, OC2-6 alkenylR₂, OC2-6 alkynyl-
 R₂, and NR₂R₂; and

“R₁₅” is selected from the group consisting of: H, C1-10 alkyl, optionally substituted
 with one or more R₁₃ groups, C1-6 acyl, optionally substituted with one or more R₁₃ groups;
 aryl; substituted aryl; arylalkyl, substituted arylalkyl; and a macrolide having the following



structure:

Scope of Withdrawn Subject Matter Not Drawn to Compound 149

The remaining subject matter of claims 1-31 that is not including in the group listed above as the elected species are withdrawn under 37 CFR § 1.142(b) as being non-elected subject matter. The compounds that are not within the elected invention, claims 3, 6, 7, 8, 14-17, 23, 25, 26, and 28, which are independent and distinct from the elected invention and do not have utility with the elected compound and are therefore withdrawn by way of restriction. Compound of Claims 1-31 are withdrawn by way of restriction are the compounds of Formula (I) that are not listed in the abovementioned scope of subject matter based on the elected species, compound 149.

The abovementioned compounds are withdrawn from consideration as being non-elected subject matter. The withdrawn compounds contain distinct substitutions such as R7, for example, where R7 is a 5-10 member heterocycle containing one or more heteroatoms selected from nitrogen, oxygen and sulfur. In this case, R7 can be 5-membered ring containing oxygen, nitrogen and sulfur, or a 7-membered ring containing 2 nitrogen atoms, or a 9-membered heterocyclic ring containing nitrogen and oxygen. These R7 groups differ significantly in structure and function. This structural and elemental variety of substitutions is exemplified by their classifications in the U.S. classification system. For example: a 7-membered ring containing 2 nitrogen atoms are classified in class 540, subclass 553+ while a 5-membered rings containing oxygen, sulfur and nitrogen are classified in class 548, subclass 122+. Therefore, compounds not drawn to the elected species are withdrawn as being non-elected subject matter that differs materially in structure and composition.

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V. REJECTIONS**Claim Rejections - 35 USC § 102**

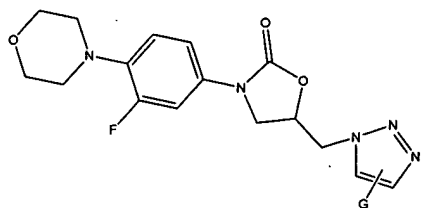
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

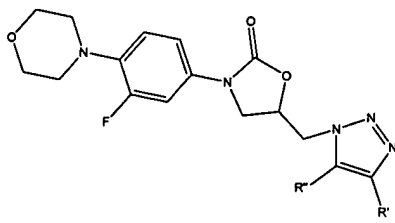
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4, 5, 9, 10, 11, 12, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Phillips, O. A.; Udo, E. E.; Ali, A. A. M.; Al-Hassawi, N. *Bioorg. & Med. Chem.* **2003** 11(1), pp. 35-41 (Available online 18 Oct. 2002).

The instant rejected claims 1, 2, 4, 5, 9, 10, 11, 12 and 13 broadly recite a compound of



the formula , wherein G is selected from a group consisting of, *inter alia*, C1-8 acyl. (See Claim 1). Phillips, et al. discloses an identical compound. Specifically,



Phillips, et al discloses, , wherein R' is CH₃CO and R'' is H.

(Phillips, et al. *Bioorg. & Med. Chem.* 2003 11(1), p. 37, scheme 1, compound No. 8 and 9).

It should be noted that Applicant claims priority to U.S. Provisional Application Nos. 60/414,207 filed 26 Sept. 2002 and 60/448,216 filed 19 Feb. 2003 under 35 U.S.C. 119(e) is acknowledged. The later-filed application must be an application for a patent for an invention

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which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 recites “a compound having the structure corresponding to any of the structures listed in Table 1.” Claim 30 recites “a compound having the structure corresponding to any of the structures listed in Table 2.” Claims shall not refer to the specification and/or drawings. See Ex parte Fressola, 27 USPQ.2d 1608, 1609 (BPAI 1993). To overcome this rejection, Applicant must amend the claims in a format that particularly defines the compounds of the invention.

Claim 13 recites the limitation “the compound according to claim 11, wherein *t* is 1.” However, claim 11 does not recite the variable “*t*.” There is insufficient antecedent basis for this limitation in the claim.

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VI. OBJECTIONS**Specification**

Applicant is reminded of the proper content of an Abstract of the Disclosure. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The abstract of the disclosure is objected to because the abstract lacks an exemplary generic structure of the compounds of the invention. Additionally, the abstract contains the numbers "2682693" at the bottom of the page, which may or may not be a typo. Correction is required. See MPEP § 608.01(b).

Claim Objection-Non Elected Subject Matter

Claims 1, 2, 4, 5, 9-13, 18-22, 24, 27, 29-31 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should rewrite instant Claims 1, 2, 4, 5, 9-13, 18-22, 24, 27, 29-31 in independent form including all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the subject matter indicated as being examinable, *supra*.

Claims 2, 4, 5, 9-13, 18-22, 24, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

VII. CONCLUSION

Claims 1, 2, 4, 5, 9, 10, 11, 12, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Phillips, et al. **Claims 29 and 30** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. **Claim 13** is objected to under 35 U.S.C. 112, second paragraph for lack of antecedent basis. **Claims 1, 2, 4, 5, 9-13, 18-22, 24, 27, 29-31** are objected to as containing non-elected subject matter. Lastly, **Claims 2, 4, 5, 9-13, 18-22, 24, and 27** are objected to as being dependent upon a rejected base claim.

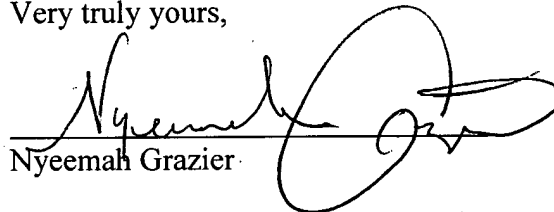
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

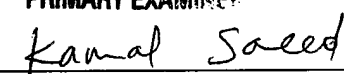
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,


Nyeemah Grazier

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